General Government Cabinet

Kentucky Board of Medical Licensure

(New Administrative Regulation)

201 KAR 9:260. Professional Standards for Prescribing and Dispensing Controlled Substances.

RELATES TO: KRS 311.530-311.620, 311.990, 218A.205

STATUTORY AUTHORITY: KRS 311.565(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licenses. This administrative regulation establishes the professional standards for prescribing and dispensing controlled substances. Each physician who is authorized to prescribe or dispense controlled substances shall conform to the following mandatory professional standards relating to controlled substances while practicing within the Commonwealth of Kentucky:

Each physician who is authorized to prescribe or dispense controlled substances shall conform to the following mandatory professional standards relating to controlled substances while practicing within the Commonwealth of Kentucky:

Section 1. Exceptions. (1) The professional standards established in this regulation shall not apply to physicians prescribing or dispensing controlled substances:

(a) to a patient as part of the patient's hospice or end-of-life treatment;

(b) to a patient admitted to a licensed hospital, during and as part of a normal and expected part of the patient's course of admission at that hospital;

(c) to a patient for the treatment of pain associated with the treatment of cancer;

(d) to a patient who is a registered resident of a skilled long-term care facility; or,

(e) as a direct part of their professional responsibilities in an emergency department and in accordance with the professional standards established in Section 5.

(2) These exceptions do not apply to the standards established in KRS 218A.172.

Section 2. Professional Standards for Initial Prescribing or Dispensing of Controlled Substances. Prior to the initial prescribing or dispensing of any controlled substance for a specific medical complaint and related symptoms, each physician shall:

(a) Verify the identity of the patient by a current and valid government-issued photographic identification. If the physician does not have a copy of that identification in the patient's medical record, that physician shall ensure that the identification is copied and placed in the patient's medical record for future reference;

(b) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and conduct a physical examination of the

patient relevant to the medical complaint and related symptoms, for all medical complaints other than psychiatric conditions, and document the information in the patient's medical record;

(c) Obtain and review a KASPER report for all available data on the patient, document relevant information in the patient's record and consider the available information to determine whether it is medically appropriate and safe to prescribe or dispense controlled substances. This requirement to obtain and review a KASPER report shall not apply to:

1. a physician prescribing or dispensing controlled substances to a patient, who is younger than eighteen (18) years of age at the time of prescribing or dispensing, for the treatment of Attention Deficit Hyperactive Disorder or Attention Deficit Disorder; or,

2. a physician prescribing or dispensing Schedule IV or V controlled substances other than those listed in this specific subsection. The physician shall obtain and review a KASPER report before initially prescribing or dispensing any of the following Schedule IV controlled substances:

(a) Ambien;

(b) Anorexics;

(c) Ativan;

(d) Klonopin;

(e) Librium;

(f) Nubain;

(g) Oxazepam;

(h) Phentermine;

(i) Soma;

(j) Stadol;

(k) Stadol NS;

(l) Tramadol;

(m) Valium;

(n) Versed; and,

(o) Xanax; or,

3. a physician who is unable to obtain and review a KASPER report in a timely manner for reasons beyond the physician's control determines, upon the available facts, that it is medically appropriate to prescribe controlled substances in the absence of a KASPER report. For this exception, the physician shall document as soon as possible the circumstances that made it impossible to obtain and review a KASPER report before prescribing and the reason(s) the physician determined it was medically appropriate to prescribe controlled substances in the absence of KASPER information.

(d) After examining the benefits and risks of prescribing or dispensing controlled substances to the patient, including non-treatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substances in the amount specified. When the identified risks are significant or unique, the physician shall document in the patient's record the reasoning underlying the decision to prescribe or dispense controlled substances in spite of those risks;

(f) Avoid providing more controlled substances than necessary by prescribing or dispensing only the amount of controlled substances needed to treat the specific medical complaint, for a definite, pre-determined time period;

(g) Not prescribe or dispense long-acting or controlled-release opioids (e.g. OxyContin, fentanyl patches, and methadone) for acute pain;

(h) Explain to the patient that controlled substances used to treat an acute medical complaint are for time-limited use, and that the patient should discontinue the use of controlled substances when the condition requiring the controlled substance use has resolved;

(i) Explain to the patient how to safely and properly dispose of any unused controlled substances.

Section 3. Professional Standards to Commence the Long-Term Use of Any Controlled Substance. Before a physician continues to prescribe or dispense any controlled substance to a patient for a medical complaint or its associated symptoms for a total period of longer than three (3) months, the physician shall comply with the following mandatory professional standards:

Patient History. (1) The physician shall obtain the following information from the patient and record all relevant information in the patient's medical record in a legible manner, in sufficient detail to provide for meaningful diagnosis and treatment of the patient, or to allow for another practitioner to assume the medical care of the patient at any given time in a safe and medically appropriate manner:

(a) History of present illness, including each of its components;

(b) Past medical history, including past diagnostic efforts and treatments for the present medical complaint and other medical complaints;

(c) History of legal or illegal substance use by the patient and by first degree relatives of patient, including treatments for abuse or dependence;

(d) Past family history of illnesses and treatment relevant to the medical complaint and related symptoms; and,

(e) Psychosocial history.

(2) If a physician's practice utilizes a patient questionnaire as a primary source of obtaining such information, the physician shall ensure that:

(a) all questions are completely answered;

(b) any material conflict in the answers is clarified with the patient;

(c) complete information is obtained regarding any significant disclosure; and,

(d) all relevant information is incorporated into the patient's record and utilized in the development of the working diagnosis.

Physical Evaluations and Assessments. (1) The physician shall conduct a comprehensive physical examination of the patient for all medical conditions and related symptoms, other than psychiatric conditions, and properly document the findings of each evaluation or assessment in the patient's record, including but not limited to:

(a) Appropriate clinical examination addressing the medical complaint and related symptoms of a sufficient degree to support the medical indications for prescribing or dispensing controlled substances on a long-term basis;

(b) Measurable examinations that will establish baselines and will assist in establishing and periodically evaluating the functional goals of any treatment plan.

(2) If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the physician shall arrange for such evaluation as quickly as possible in order to be able to incorporate the findings into the working diagnosis and treatment plan. The physician shall document the relevant information obtained from the evaluation. If the physician determines that such an evaluation is necessary and the patient declines or fails to complete the evaluations in a timely manner for any reason, then the physician shall not continue the use of controlled substances unless the physician determines that continued use of controlled substances is safe and medically appropriate in the absence of such information. In that event, the physician shall document the reasons that the patient failed to complete the evaluation and the reasoning supporting the continued use of controlled substances in the absence of that relevant information;

Obtaining Medical Records from Other Practitioners. (1) If the physician determines that the patient has previously received medical treatment for the presenting medical complaint or related symptoms and that review of the prior treatment records is necessary to justify long-term prescribing of controlled substances, the physician shall request a copy of the other physician's records regarding the patient as quickly as possible, in order to incorporate such information into the working diagnosis and treatment plan;

(2) If the physician has requested a copy of the other physician's records and has not received them within a reasonable time, the physician will take appropriate steps to follow up and obtain such records. If the physician is unable, after reasonable attempts, to obtain the relevant records, the physician shall document the efforts made to obtain the records, the failure to receive the records, and the impact the inability to obtain such records has upon the physician's decision whether to continue or modify treatment, particularly the use of controlled substances, for that patient;

(3) Each physician, who receives a written request from another physician for a copy of records relating to that physician's prior treatment of a specific patient, shall promptly provide a copy of the patient's medical record to the requesting physician.

Establishing a Working Diagnosis. (1) Based upon consideration of all information available, the physician shall promptly formulate and document a working diagnosis of the source of the patient's medical complaint and related symptoms. It is not sufficient to simply describe or list the related symptoms;

(2) If the physician is unable, despite best efforts, to formulate a working diagnosis, the physician shall consider the usefulness of additional information, such as specialized evaluations or assessments, referral to appropriate specialists, usefulness of further observation and evaluation, before attempting again to formulate a working diagnosis;

(3) If the physician is unable, despite best efforts, to formulate a working diagnosis, the physician must determine whether long term use of controlled

substances is indicated and appropriate. The physician may determine that a different or lower level of treatment is more appropriate until a working diagnosis can be established;

(4) The physician shall document the working diagnosis or all of the efforts taken in their unsuccessful attempt to formulate a working diagnosis and the reasons for their decision whether or not to utilize controlled substances on a long-term basis in the absence of a working diagnosis.

Formulating a Treatment Plan. (1) The physician shall formulate and document in the patient's medical record the proposed treatment plan, based upon the working diagnosis of the medical complaint and related symptoms, along with relevant baseline information obtained in the evaluation of the patient;

(2) The treatment plan shall include specific and verifiable goals of treatment, with a schedule for periodic evaluations, which will permit the physician to assess whether a treatment is appropriately addressing the medical complaint and improving the patient's functional abilities. Statements such as "treat [medical] condition and related symptoms", "to make patient feel better," or "prescribe controlled substances" are not sufficient treatment goals. The treatment plan shall include an exit strategy for the termination of use of any treatment modality, including controlled substances, for appropriate reasons;

Patient Screening. (1) The physician shall utilize appropriate screening tools to screen each patient to determine if the patient:

(a) is presently suffering from abuse or dependence of any substance, including alcohol;

(b) is presently suffering from a psychiatric or psychological condition that requires treatment or that may impact the patient's treatment with controlled substances; or

(c) presents a significant risk for illegal diversion of controlled substances, based upon information, gained by obtaining and reviewing a current KASPER report for all available data on that patient, that the patient has obtained controlled substances from multiple practitioners or has refilled prescriptions for controlled substances inappropriately.

(2) If, after screening, the physician determines that there is a reasonable likelihood that the patient suffers from substance abuse or dependence, the physician shall refer the patient to an appropriate treatment program or provider, or to an addiction specialist. If, after screening, the physician determines that there is a reasonable likelihood that the patient suffers from a qualifying psychiatric or psychological condition, the physician shall refer the patient for a psychological or psychiatric consultation, if appropriate. After making such referral, the physician shall consider the recommendations of the treatment program or specialist, before determining whether to continue with the long-term use of controlled substances with that patient, and, if so, appropriate treatment measures and monitoring. The physician shall document all relevant information about the screen, the referral, the recommendations, and any resulting prescribing decisions in the patient's medical record;

(3) If, after screening, the physician determines that there is a significant likelihood that the patient may illegally divert controlled substances, the physician

must determine whether the use of a "prescribing agreement" would be sufficient to prevent diversion. This determination necessarily requires the physician to determine whether they have the professional resources to conduct necessary monitoring of the patient's controlled substance use. The terms of a "prescribing agreement" shall include, but not be limited to the patient's agreement to:

(a) avoid improper use of controlled substances;

(b) identify other licensed professionals providing medical care to the patient and authorize the physician to communicate with these other providers to coordinate care, particularly prescribing or dispensing of controlled substances;

(c) only obtain controlled substances from the designated physician;

(d) only fill controlled substances prescriptions at an approved pharmacy;

(e) submit to urine drug screens or pill counts on request;

(f) not seek early refills or call-in prescriptions of controlled substances;

(g) to produce an official police report for any effort to replace controlled substances that were lost or stolen;

(h) if necessary, submit to third-party administration of controlled substances prescribed if determined appropriate.

In order to avoid confusion and for the benefit of both parties, the physician shall consider including in the agreement the consequences for a violation of each provision. The "prescribing agreement" and informed consent document may be combined into one document.

(4) The physician shall obtain and document a baseline urine drug screen to determine whether the medications that are being prescribed are in the patient's

system and to determine whether any un-prescribed or illegal controlled substances are in the patient's system.

(5) If, after screening, the physician determines that the controlled substances prescribed to the patient will be used or are likely to be used other than medicinally or other than for an accepted therapeutic purpose, the physician shall not prescribe controlled substances to that patient;

Obtaining Informed Consent. (1) The physician shall explain the risks and benefits of long term use of controlled substances and obtain informed consent from the patient for such prescribing. The decision to provide controlled substances to a patient on a long-term basis should be a deliberate and conscious decision by both the physician and the patient, after full consideration of the risks and benefits of such treatment;

(2) After explaining the risks and benefits of long-term use of controlled substances, the physician shall obtain the informed consent of the patient, in a writing that specifically sets out each risk and benefit discussed with the patient, and shall include and maintain that written informed consent in the patient's medical record. The informed consent document and any "prescribing agreement" may be combined into one document.

Initial Trial of Other Treatments; Titration. (1) Controlled substances shall only be utilized on a long-term basis after other appropriate non-controlled therapies have been attempted and have proven unsuccessful in appropriately treating the medical complaint and related symptoms. If controlled substances are utilized on a long-term basis, the physician shall prescribe or dispense

controlled substances at the lowest level and for the shortest duration necessary to appropriately treat the medical complaint and related symptoms;

(2) The physician shall initially attempt, to the extent possible, or to establish and document a previous attempt by another physician, in increasing order, the following steps to treat the medical complaint and related symptoms:

(a) Use of physical therapy modalities alone or use of non-steroidal anti-inflammatory medication alone;

(b) Use of physical therapy modalities in conjunction with non-steroidal anti-inflammatory medication;

(c) Use of lowest level of controlled substances considered effective to treat the medical complaint and related symptoms, as part of an opioid trial; and,

(d) Titration of levels of controlled substances in measured steps until the level of controlled substances adequately treats the medical complaint and related symptoms.

Section 4. Professional Standards for Long-Term Prescribing or Dispensing of Controlled Substances. If a physician continues to prescribe or dispense controlled substances beyond three (3) months for a specific medical complaint and related symptoms, the physician shall comply with the following mandatory professional standards:

Patient Visits. (1) The physician shall personally see the patient at least once a month initially for evaluation and review of progress. The physician may see the patient less frequently, on a schedule determined by the physician's professional judgment after the physician has determined:

(a) the controlled substances prescribed or dispensed have been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms;

(b) the controlled substances prescribed or dispensed are not causing harmful side effect; and,

(c) there is sufficient monitoring in place to ensure that the patient will not use the controlled substances in an improper or inappropriate manner or divert them for an improper or inappropriate use.

(2) At each patient visit, the physician shall obtain a current history from the patient, shall conduct a focused physical examination, and shall perform appropriate measurable examinations as indicated in the treatment plan. The physician shall document all relevant information into the patient's medical record;

(3) At each patient visit, the physician shall evaluate the working diagnosis and treatment plan based upon the information gained during that encounter to determine whether there has been functional improvement or any change in baseline measures. If appropriate, the physician shall modify the diagnosis or treatment plan, or both, as appropriate. The reasons for any modification shall be documented in the patient's medical record.

Reviewing Functional Goals; Specialty Consultations. (1) The physician shall regularly review and determine whether the patient is exhibiting improved function, by meeting treatment goals jointly set, and is responding favorably to the medical treatment, including controlled substance therapy;

(2) For patients presenting a significant risk of diversion or improper use of controlled substances, the physician shall obtain the patient's consent to discuss the patient's treatment with independent sources, including family members, in order to verify:

(a) the patient's progress toward or achievement of treatment goals; and,

(b) the patient's use of controlled substances and any side effects of that use, through independent sources;

(3) If the medical complaint and related symptoms continue with no significant improvement in function despite treatment with controlled substances, the physician shall obtain consultative assistance to determine whether there are undiagnosed conditions that must be addressed to resolve the medical complaint, such as psychiatry, neurology, internal medicine, physical medicine and rehabilitation, orthopedics, addiction medicine, rheumatology, or oncology;

(4) For patients exhibiting symptoms suggestive of mood, anxiety and/or psychotic disorders, the physician shall obtain psychiatric or psychological consultations for intervention if such condition is affecting treatment;

Managing Breakthrough Pain. (1) If a patient reports that they are experiencing episodes of "breakthrough" pain, the physician shall:

(a) attempt to identify the trigger or triggers for such episodes;

(b) determine whether the breakthrough pain may be adequately treated through non-controlled treatment;

(c) if the episodes continue and the non-medication treatments do not adequately address the triggers, and after considering the risks and benefits, the

physician determines to add an as-needed controlled substance to the regimen, the physician must take appropriate steps to minimize the improper or illegal use of the additional controlled substances by prescribing or dispensing only the amount of controlled substances needed to treat the specific medical complaint, for a definite, pre-determined time period. The physician shall also include appropriate monitoring of the additional controlled substance;

Preventive Medicine. (1) At least once a year, the physician shall perform or shall ensure that the patient's primary treating physician performs preventive health screening and physical examination appropriate to the patient's gender, age, and medical condition. The physician shall ensure that the patient is provided treatment appropriate to the findings and results of such screening. The physician shall document in the patient's medical record the annual preventive health screening performed or the results of the screening performed by the primary treating physician, the findings and results, and the treatment provided, if any;

Periodic KASPER Reviews and Monitoring Adherance. (1) At least once every three months, the physician shall obtain and review a current KASPER report to ensure that the patient is properly filling the prescriptions issued and that the patient is not obtaining controlled substances from other practitioners without the physician's knowledge and approval;

(2) If, at any time while the physician is prescribing or dispensing controlled substances to a patient, the physician obtains or receives specific information that the patient is not taking the controlled substances as directed, is diverting

controlled substances, or is engaged in any improper or illegal use of controlled substances, the physician shall immediately obtain and review a KASPER report for the purposes specified in subsection (1), supra;

(3) If a KASPER report discloses that the patient is not filling the controlled substance prescriptions as directed or is obtaining controlled substances from other practitioners without the prescribing physician's knowledge and approval, the physician shall immediately address those issues with the patient. The physician shall not prescribe or dispense any more controlled substances unless the physician has addressed the issues with the patient and has determined that it is medically appropriate and safe to continue prescribing or dispensing controlled substances to the patient;

(4) If a KASPER report discloses that the patient is obtaining controlled substances from other practitioners without the physician's knowledge and approval, the physician shall promptly notify the appropriate law enforcement agency and the other practitioners of the relevant information from the KASPER review;

(5) The physician shall document in the patient's medical record each time a KASPER review is performed, information obtained; and, if applicable, the patient's account of any irregularities noted in the review; and, the physician's determination of what actually occurred;

(6) If the physician should determine that it is medically appropriate and safe to continue or resume prescribing or dispensing controlled substances to the patient after assessing their failure to fill prescriptions as directed or their

obtaining controlled substances from other practitioners without the prescribing physician's knowledge and approval, the physician shall fully document in the patient's medical record the physician's rationale for resuming such prescribing or dispensing, to include an analysis of the risks and benefits of that decision, along with the increased monitoring or oversight measures being put into place to ensure controlled substances are not illegally diverted or used;

(7) The physician shall obtain consultative assistance from a specialist when appropriate.

Random Pill Counts. (1) When appropriate, the physician shall conduct unannounced random pill counts to determine whether the patient is taking the controlled substances as directed;

(2) If the physician discovers irregularity in the pill count, the physician shall immediately address those findings with the patient. The physician must use all available information, including a discussion with the patient, to determine whether the patient is illegally diverting controlled substances;

(3) If the physician determines that the patient has diverted controlled substances, the physician should immediately discontinue the prescribing or dispensing of controlled substances to that patient, if medically feasible. If it is not medically feasible to immediately discontinue the prescribing or dispensing of controlled substances, the physician shall immediately begin a tapering process to safely discontinue prescribing or dispensing controlled substances, after putting in place specific protections that will ensure that no further diversion occurs, such as requiring storage and administration of the controlled substances

to the patient by a person designated by the physician, with additional random pill counts;

(4) The physician shall fully document the results of each pill count conducted, the physician's determination of the reasons for any shortage, and the physician's decisions regarding continued treatment, in the patient's medical record.

Urine Drug Screens. (1) During the course of long-term prescribing or dispensing of controlled substances, the physician shall utilize urine drug screens in a random manner at appropriate times to determine whether the patient is taking prescribed medications or taking illegal substances or medications not prescribed by the physician.

(2) If the patient tested negative for controlled substances prescribed or dispensed by the physician and confirmatory testing substantiates a "red flag," the physician shall do one of the following:

(a) do a controlled taper;

(b) stop prescribing or dispensing controlled substances immediately; or,

(c) refer the patient to an addiction specialist or drug treatment program, depending upon the circumstances.

(3) The physician shall discontinue controlled substance treatment and/or refer the patient to addiction management if one or more of the following conditions exist:

(a) There has been no improvement in function and response to the medical complaint and related symptoms;

(b) Controlled substance therapy has produced significant adverse effects; and/or

(c) The patient exhibits drug-seeking behavior or diversion.

Section 5. Professional Standards for Prescribing or Dispensing Controlled Substances in an Emergency Department Setting. The following professional standards apply to physicians who prescribe or dispense controlled substances in an emergency department setting:

(1)Before prescribing or dispensing a controlled substance in an emergency department setting, the physician shall:

(a) Obtain an appropriate medical history relevant to the medical complaint and conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record;

(b) Obtain and review a KASPER report for all available data on the patient, document relevant information in the patient's record, and consider the available information to determine whether it is medically appropriate and safe to prescribe or dispense controlled substances. If the physician cannot obtain a KASPER report for review in sufficient time to make the determination whether to prescribe or dispense controlled substances, the physician shall not prescribe or dispense controlled substances unless demonstrated and documented in the patient's medical record that the medical necessity for and safety in prescribing or dispensing the controlled substance substantially outweigh the risk of unlawful

use or diversion of the controlled substances, particularly considering the nature and severity of the patient's presenting complaint;

(c) After examining the benefits and risks of prescribing or dispensing controlled substances to the patient, including non-treatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substances in the amount specified, and document that decision in the patient's record and, if appropriate, the reasoning underlying that decision.

(2) The physician is strongly discouraged from and shall not routinely:

(a) Administer intravenous and/or intramuscular controlled substances for the relief of acute exacerbations of chronic pain;

(b) Provide replacement prescriptions for controlled substances that were lost, destroyed, or stolen;

(c) Provide replacement doses of methadone, suboxone, or subutex for patients in a treatment program;

(d) Prescribe long-acting or controlled-release controlled substances, such as OxyContin, fentanyl patches, or methadone or replacement doses of such medications;

(e) Administer Demerol (Meperadine) to the patient;

(f) Prescribe or dispense more than a three (3) day supply of controlled substances, with no refills.

(3) If the physician determines that exceptional circumstances exist which warrant prescribing or dispensing controlled substances in a manner that is

strongly discouraged in Section 2(1), supra, the physician shall document in the patient's medical record the exceptional circumstances that warranted such prescribing or dispensing.

(4) The physician shall ensure that each patient receiving controlled substances by dispensing or prescription is given is informed, by handout or display signage, of the standards established in this regulation regarding the prescribing or dispensing of controlled substances.

(5) These standards shall not apply or be enforced during periods involving disaster, mass casualties, or extreme emergency.

Section 6. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes and Monitoring. (1) Each physician shall document all relevant information in a patient's medical record in a legible manner and in sufficient detail to provide for:

(a) meaningful diagnosis and treatment of the patient;

(b) the safe and medically appropriate assumption of care by another physician at any given time; and,

(c) this board to determine whether the physician is conforming to professional standards for prescribing or dispensing controlled substances and other relevant professional standards.

Such information includes, but is not limited to:

(a) Medical history and physical examinations;

(b) Diagnostic and laboratory test results and therapeutic outcomes;

(c) Evaluations and consultations;

(d) Records of past treatment outcomes including indicators of benefits, such as functional outcomes, and indicators of risk, such as adverse effects;

(e) Medications (including date prescribed, type, dosage, strength and quantity);

(f) Intensity levels of medical complaint and related symptoms;

(g) Subjective complaints of the patient;

(h) Objective findings related to subjective complaints, including impact on functioning and quality of life;

(i) Diagnostic impressions, and potential treatment options;

(j) Treatment objectives;

(k) Discussion of risks and benefits;

(l) Informed consent;

(m) Instructions and agreements; and

(n) Periodic review of treatments, including adverse effects, functional goals, and any other outcomes that reflect benefits or problems with the treatment.

(2) If a physician is unable to conform to professional standards for prescribing or dispensing controlled substances, to the professional standards established by KRS 218A.172, or to other professional standards, due to circumstances beyond their control, the physician shall appropriately document such circumstances and the physician's response to the inability to conform to the specific standards and the impact upon the continuing care of the patient.

Section 7. Responsibility to Educate Patients Regarding the Dangers of Controlled Substance Use. (1) It is the acceptable and prevailing medical practice within the Commonwealth of Kentucky for physicians prescribing or dispensing controlled substances to educate patients receiving controlled substances about the following subjects through verbal or written counseling:

(a) proper use;

(b) impact upon driving and work safety;

(c) effect of use during pregnancy;

(d) potential for overdose and appropriate response to overdose;

(e) safe storage of controlled substances;

(f) proper disposal;

(2) Educational materials relating to these subjects may be found on the board's website, www.kbml.ky.gov and are incorporated by reference into this provision.

Section 8. Violations. (1) Any violation of the professional standards established in this regulation or in KRS 218A.172 shall constitute a violation of KRS 311.595(12) and (9), which may result in the imposition of disciplinary sanctions pursuant to KRS 311.595;

(2) Each violation of the professional standards established in this regulation or in KRS 218A.172 shall be established by expert testimony by one or more physicians retained by the board, following a review of the licensee's patient records and other available information including KASPER reports.

Adopted:

7/20/12
DATE

PRESTON P. NUNNELLEY, M.D., PRESIDENT
KENTUCKY BOARD OF MEDICAL LICENSURE

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on September 27, 2012 at 9:30 a.m. at the offices of the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by September 20, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until October 1, 2012. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: C. Lloyd Vest II, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7150, fax (502) 429-7118.

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Contact Person: C. Lloyd Vest II, General Counsel, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222: (502) 429-7150.

(1) Provide a brief summary of:
   (a) What this administrative regulation does: This administrative regulation establishes professional standards for prescribing and dispensing controlled substances in the Commonwealth of Kentucky.
   (b) The necessity of this administrative regulation: It is necessary to promulgate this regulation to establish professional standards for prescribing and dispensing controlled substances in the Commonwealth of Kentucky.
   (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation acts specifically to establish professional standards for prescribing and dispensing controlled substances in the Commonwealth of Kentucky.
   (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation acts specifically to establish professional standards for prescribing and dispensing controlled substances in the Commonwealth of Kentucky.

(2) If this is an amendment to an existing regulation, provide a brief summary of:
   (a) How the amendment will change this existing administrative regulation; Not Applicable.
   (b) The necessity of the amendment to this administrative regulation; Not Applicable.
   (c) How the amendment conforms to the content of the authorizing statutes; Not Applicable.
   (d) How the amendment will assist in the effective administration of the statutes. Not Applicable.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect every physician that prescribes and dispenses controlled substances in the Commonwealth of Kentucky.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this regulation, if new, or by the change, if it is an amendment, including:
   (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Applicants will be required to follow the professional

standards for prescribing and dispensing controlled substances in the Commonwealth of Kentucky.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no cost associated with the requirements of this administrative regulation known to the Board.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Benefits to the physician include having professional standards for prescribing and dispensing controlled substances to help curb the prescription drug epidemic in the Commonwealth of Kentucky.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: None

(b) On a continuing basis: None

(6) What is the source of funding to be used for the implementation and enforcement of this administration regulation: None.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase of fees or funding will be necessary.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish any fees nor does it directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? (Explain why or why not)

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 201 KAR 9:260
Contact Person: C. Lloyd Vest II
Phone number: 502/429-7150

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? None

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.
KRS 311.565(1)(a), 218A.205

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None

(c) How much will it cost to administer this program for the first year? None

(d) How much will it cost to administer this program for subsequent years? None

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):
Expenditures (+/-):
Other Explanation: